Dermatology
beyond the skin

COLLABORATION AGREEMENT
(PATIENT ORGANIZATIONS) CONSULTANCY SERVICES

between

Atopisk Eksem forening (AEF)

and

LEO PHARMA A/S

TABLE OF CONTENS

LIST OF SCHEDULES

SCHEDULE A:	LEO HCP/HCO Compliance Protocol for Third Parties

THIS AGREEMENT ("**Agreement**") is made and entered into by and between:

(1) **LEO Pharma A/S**, a company organized and existing under the laws of Denmark and having its registered office at Industriparken 55, 2750 Ballerup, Denmark, with its company registration no. 56759514 ("**LEO Pharma**"), and

(2) **Atopisk eksem forening**, an organization organized and existing under the laws of Denmark and having its registered office at Frikvarteret 2, 2. lejlighed 13, 3600 Frederikssund, Denmark ("**Patient Organization**"),

hereinafter individually referred to as "**Party**" and collectively as "**Parties**",

WHEREAS:

(A) LEO Pharma is a research-based pharmaceutical company that develops, manufactures and markets pharmaceutical products to patients within dermatology and thrombosis.

(B) The Patient Organization is an organization working with support and education of relatives and patients diagnosed with Atopisk dermatitis.

(C) LEO Pharma wishes to engage the Patient Organization to provide services within the unique expertise as a patient to map out the patient journey in two aspects. One is the actual journey throughout the healthcare system. The other is the emotional journey the patient undertake during the disease pathway. ("**Services**") and the Patient Organization wishes to provide such Services to LEO Pharma.

NOW THEREFORE, the Parties have agreed as follows:

1 PURPOSE

1.1 The purpose of this Agreement is to describe the terms and conditions for the collaboration between the Parties in connection with Services to be provided to LEO Pharma and its Affiliates by the Patient Organization. For the purpose of this Agreement **"Affiliate"** is defined as any company, corporation, firm, partnership or other entity controlling or controlled by LEO Pharma.

2 THE SERVICES

2.1 Currently there exist no data on the AD patient journey in DK and in order for LEO pharma to understand the disease pathway, we need to collect insights coming from patients diagnosed with AD. This collaboration is an engagement with AEF aiming to map the patient journey within AD, seen both from patient perspective and from the HCP perspective.

- AEF will support a workshop in Copenhagen with participation of 3 patients (with 3 different patient profiles to fully understand the pathway)
- October 5th, 2020 from 10.00 – 16.00 including light lunch
- Full Day Workshop – moderated by Advice Gammel Kongevej 3E, Baghuset, 1610 København V.
- Anne Skov Vastrup will as chairman of the AEF engage 3 patients from the association

- AEF, Frikvarteret 2, 2. lejlighed 13, 3600 Frederikssund, Denmark
- Identification of 3 patients prior to the meeting
- Participation of the 3 patients in the workshop October 5th, 2020

2.1 The Patient Organization represents and warrants to comply with any and all applicable laws, rules, regulations, government regulatory requirements and guidelines in force from time to time in connection with the Services.

2.2 The Patient Organization acknowledges that LEO Pharma has committed to comply with a number of national and international industry ethical codes including but not limited to:

- the International Federation of Pharmaceutical Manufactures and Associations Code of Practice (the **IFPMA Code**);
- The EFPIA Code of Practice
- the EFPIA Code of Practice on Relationships between the Pharmaceutical industry and Patient Organisations;
- the European Pharmaceutical Market Research Association's (EphMRA) Code of Conduct;
- the Danish Ethical Committee for the Pharmaceutical Industry (ENLI) Code of Practice on Promotion etc., of Medicinal Products aimed at Healthcare Professionals;
- the ENLI Ethical Rules for Collaboration between Patient Organizations, etc., and the Pharmaceutical Industry; and
- the ENLI Ethical Rules for Negotiations with Decision-makers (Lobbying Code).

The Patient Organization therefore undertakes to comply with these ethical codes to the extent they would apply to LEO Pharma in connection with the Services.

2.3 The Patient Organization and its representatives shall at all times conform to the LEO Pharma Third Party Compliance Code as set out from time to time at www.leo-pharma.com/thirdparty ("**Compliance Code**"). Upon request, the Patient Organization shall provide information on its level of compliance with the Compliance Code so that LEO Pharma can assess whether the Patient Organization actually complies with the Compliance Code, or not. The Patient Organization shall at all time and promptly take all appropriate steps to resolve and correct any identified non-conformity.

2.4 To the extent required, the Patient Organization shall be responsible for obtaining and maintaining all consents and permissions necessary for the performance of the Services.

2.5 Contact persons in matters related to this Agreement:

From LEO Pharma:	Annette Giversen, Market access manager Email: angiv@leo-pharma.com
From the Patient Organization:	Anne Skov Vastrup Email: anne@vastrup.dk

3 REMUNERATION

3.1 (**Fees**) The fees for the Services and the rights assigned to LEO Pharma and/or its Affiliates under this agreement: shall be 12.600 kr, (3 ptt ' 6 hours hourly rate 700 dk) which is representative of the fair market value for such Services, including but not limited to all preparatory work, travel time, meeting time, materials, results, deliverables etc. for all representatives. The Fees payable are exclusive of VAT and any other local taxes. The Patient Organization shall not be entitled to any additional payments unless agreed upon between the Parties in writing. LEO Pharma shall be contacted immediately if the Patient Organization estimates that more hours than agreed are required to perform the Services.

3.2 (**Invoices**)The Patient Organization shall send invoices no later than sixty (60) days after the Services have been performed. The Patient Organization shall issue invoice(s) to LEO Pharma A/S, Att.: Annette Giversen, Industriparken 55, 2750 Ballerup, Denmark. Invoices and expense receipts should be sent as a PDF file to angiv@leo-pharma.com, marked "Patient journey workshop" in the subject line in order to receive payment and reimbursement.

The invoice shall include following information:

- LEO Pharma A/S VAT no: DK 56759514
- Name and address of the Patient Organization
- Invoice number and date
- Specification of the Services and time spent
- Invoice currency
- Bank details
- Patient Organization VAT number (EU countries) if applicable
- If the Services are subject to VAT or any other local taxes, any mandatory data in accordance with the provisions of the applicable VAT or tax laws.

Payment terms are date of invoice plus thirty (30) days.

3.3 (**Travel and accommodation**) LEO Pharma will arrange hotel accommodation and book the necessary and relevant transportation, if not otherwise agreed.

LEO Pharma will not reimburse any accommodation and travel booked by the Patient Organization, without prior written approval, and will in no event be able to refund any costs without proper documentation.

The following reasonable and documented travel and accommodation costs shall be covered by LEO Pharma:

Accommo-dation	None	None
Travel costs	Travel cost will be reimbursed	As booked by the Patient Organi-zation

The Parties represent and warrant that neither this Agreement nor any amount paid or reimbursed by or on behalf of LEO Pharma is intended to be, nor shall it be construed as, an offer or payment made, whether directly or indirectly, to recommend, arrange for, induce or reward the referral of patients, the purchase, lease or order of any product or service or the promotion of the interest of LEO Pharma.

4 INTERACTION WITH HEALTHCARE PROFESSIONALS ("HCPS"), HEALTHCARE ORGANIZATIONS ("HCOS") AND THE GENERAL PUBLIC

The Patient Organization may in connection with the Services interact with or engage HCPs and/or HCOs. The Patient Organization acknowledges that LEO Pharma and its Affiliates may be required by applicable law, regulations, industry codes and/or internal procedures to comply with certain requirements for engagement, payment or provision of other transfers of value ("**ToVs**") to HCPs and HCOs. These requirements may also apply to engagements of and ToVs to HCPs/HCOs by the Patient Organization in connection with the performance of the Services.

In order to ensure compliance with the above mentioned requirements, including the ethical industry codes mentioned in Clause 2.2, the Patient Organization agrees to comply with the procedures set out in the LEO HCP/HCO Compliance Protocol for Third Parties which can be found on the LEO Pharma corporate website here: https://www.leo-pharma.com/our-responsibility/hcps-and-healthcare-organizations as this may be updated from time to time. In addition, the current version is attached to the Agreement as Schedule A. The Additional requirements and internal approval procedures of LEO Pharma may apply for HCPs/HCOs from certain countries. Time for required approval and compliance shall be taken into consideration by the Patient Organization when planning the performance of the Services. Applicable requirements and procedures for each relevant jurisdiction must be agreed in writing.

4.2 The Patient Organization acknowledges that the promotion of prescription only products towards the general public is prohibited in most countries. If the Patient Organization in connection with the Services on behalf of LEO Pharma shall interact with or as part of the Services shall provide materials targeted at the general public, the Patient Organization shall ensure that such interactions and materials are compliant with all relevant laws, regulations and ethical guidelines applicable to the pharmaceutical industry's interaction and communication with the general public as well as any procedures agreed between the Parties to ensure such compliance.

5 INTELLECTUAL PROPERTY RIGHTS

5.1 Any and all information of any kind provided and/or disclosed by or on behalf of LEO Pharma in connection with the Services ("**LEO Pharma Information**") is the exclusive property of LEO Pharma and nothing in this Agreement shall be construed as granting the Patient Organization any license or proprietary right with respect to LEO Pharma Information.

5.2 Any and all results including, but not limited to reports, documents and any other work product as well as all intellectual property rights, inventions (whether patentable or not) and know-how generated and/or resulting from the Services ("**Results**"), shall be the exclusive property of LEO Pharma, who shall be entitled to use Results without any restrictions. Nothing in this Agreement shall be construed as granting to the Patient Organization any license or proprietary right hereto.

6 CONFIDENTIALITY

6.1 Any and all Results, LEO Pharma Information and other business information or materials (whether or not patentable) of LEO Pharma, its Affiliates or a third party, whether in written, graphical, electronic or oral form or in any other medium disclosed to, communicated to, learned of or otherwise acquired by the Patient Organization under this Agreement except for information which Patient Organization is able to prove is already lawfully in its possession prior to disclosure

under this Agreement or is or becomes public knowledge through no fault of the Patient Organization shall be considered as confidential information ("**Confidential Information**").

6.2 The Patient Organization shall use the Confidential Information solely in connection with the Services and shall not disclose or exploit, whether directly or indirectly, any Confidential Information for its own benefit or the benefit of any third party (person or entity).

6.3 The Patient Organization shall maintain the Confidential Information in confidence for a period of five (5) years from the date of disclosure, and shall upon termination or expiry of this Agreement, if requested by LEO Pharma, promptly return, delete or destroy (at the discretion of LEO Pharma) all Confidential Information in its possession, including all copies, reproductions and summaries thereof.

7 TRANSPARENCY AND DISCLOSURE

7.1 LEO Pharma must annually publish a list on its website of the Patient Organizations LEO Pharma have engaged to provide paid-for services. The Patient Organization consents to disclosure of information on such list about this Agreement, including a description of the services and any payments made by LEO Pharma under the Agreement as well as disclosure of the total amount LEO Pharma has paid to the Patient Organization during the year.

7.2 LEO Pharma encourages the Patient Organization to declare that it has provided paid services to LEO Pharma whenever the Patient Organization communicates in public on any matter that is related to the Services or any other issue related to LEO Pharma.

8 USE OF THE PATIENT ORGANIZATION'S LOGO

8.1 The Patient Organization agrees that LEO Pharma may use the Patient Organization's logo or name, and make use of collaboration with the Patient Organization, as follows: [insert – e.g. to be mentioned on the website of LEO Pharma

9 INDEPENDENCE AND CONFLICT OF INTEREST

9.1 The Parties declare by signing this Agreement that the Patient Organization shall be free to collaborate with other pharmaceutical companies and that LEO Pharma shall be free to collaborate with other Patient Organizations. The Parties further state that their collaboration shall not involve exclusive rights with respect to specific product or therapeutic areas or do not include any obligation or inducement to recommend a particular medicinal product.

9.2 LEO Pharma agrees by signing this Agreement not to impose conditions for the Patient Organization's professional or stakeholder-policy viewpoints. This Agreement shall not be seen as explicit or implicit agreements that confer an obligation on the Patient Organization to recommend or in any other way promote the interest of LEO Pharma.

10 TERM AND TERMINATION

10.1 This Agreement shall come into force on the day of the last signature to the Agreement and shall unless terminated earlier, remain in force until the Services have been completed, at which date the Agreement shall be terminated automatically.

10.2 If the Patient Organization breaches any of its obligations under this Agreement, LEO Pharma may terminate the Agreement with immediate effect and be entitled to seek other legal redress in Danish law for breach of agreement, including a claim for compensation irrespective of whether the Agreement shall have been terminated.

11 DATA PROTECTION

11.1 The Parties undertake at all time to comply with all applicable laws and regulations applicable to the processing of personal data and data protection.

12 LAW AND VENUE

12.1 This Agreement shall be governed by the laws of Denmark without regard to the conflict of law provisions.

12.2 Any dispute arising out of or in connection with this Agreement, including any disputes regarding the existence, validity or termination thereof, shall be settled by arbitration administrated by the Danish Institute of Arbitration in accordance with the rules of arbitration procedure adopted by the Danish Institute of Arbitration and in force at the time when such proceedings are commenced. The arbitral tribunal shall be composed of three arbitrators. Each Party shall appoint one arbitrator, and the Danish Institute of Arbitration shall appoint the chairman of the arbitration tribunal. If a Party has not appointed an arbitrator within thirty (30) business days of having requested or received notice of the arbitration, such arbitrator shall be appointed by the Danish Institute of Arbitration. The place of arbitration shall be Copenhagen, Denmark and the arbitration shall be conducted in English.

13 SIGNATURES

13.1 The Agreement may be executed in one or more counterparts, each of which shall be an original and all of which shall constitute together the same document. The Parties agree that the execution of this Agreement by standard industry signature software and/or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures. Any amendments of the Agreement shall be in writing and signed by authorized representatives of the Parties.

LEO Pharma A/S	Atopisk eksem forening
Date:	Date:
_____	_____
Name: Klaus Abel	Name: Anne Skov Vastrup
Title: Managing Director, LEO Pharma AB	Title: Chairman of Atopisk eksem forening

Schedule A

Dermatology beyond the skin

LEO Pharma HCP/HCO Compliance Protocol for Third Parties

1 Purpose of the HCP/HCO Compliance Protocol

The purpose of this HCP/HCO Compliance Protocol is to outline the specific requirements that you, as a Third Party, must adhere to when interacting with HCPs/HCOs in connection with services performed for or on behalf of LEO Pharma.

For interactions with HCPs/HCOs from some countries, additional requirements or internal approval procedures of LEO Pharma may apply.

The requirements and procedures for each relevant country shall be described in the contract with LEO Pharma.

You are not allowed to interact with HCPs/HCOs from countries where the compliance requirements have not been specified in the agreement or otherwise have been agreed in writing.

For double-blinded activities as described in section 6, only section 1 and section 6 is applicable.

2 HCP/HCO Engagements

Any interactions that Third Parties have with HCPs and HCOs in connection with services performed for or on behalf of LEO Pharma must comply with the ethical codes of the European Federation of Pharmaceutical Industries and Associations (EFPIA) & the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) to which LEO Pharma is committed, as well as any other applicable national laws, requirements and/or codes. This means that you must ensure that:

- HCPs/HCOs are only engaged if there is a documented legitimate need for the services to be performed by HCPs/HCOs
- the HCPs/HCOs chosen to perform the services are selected based on appropriate qualifications
- the number of HCPs/HCOs retained is not greater than the number reasonably necessary to achieve the identified need
- fees and expenses are reasonable and constitute fair market value
- travel and hospitality provided to HCPs or representatives of HCOs comply with this compliance protocol
- HCPs/HCOs are only engaged for services/activities (or otherwise provided funding) for the purpose of supporting healthcare or research
- engagements of HCPs/HCOs never constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.
- a contract with the HCP/HCO is signed prior to initiating the service/activity
- in countries with disclosure requirements, the right to process and transfer (spend) data relating to the HCP/HCO to LEO Pharma is obtained

- in countries with consent requirements, the HCP/HCO is informed that LEO Pharma may collect consent for the disclosure of spend data directly from the HCP/HCO at any given point in time prior to disclosure
- you are able to capture and track any transfers of value made to the HCP/HCO and collect consent from the HCP/HCO, if requested by LEO Pharma.

3 Travel and Hospitality

All forms of travel and hospitality offered to HCPs and representatives of HCOs must be solely related to the main purpose of the service/activity to be performed.

Hospitality must:

- be appropriate and within a reasonable in level
- be strictly limited to travel, meals and accommodation
- only be provided to persons who qualify as meeting participants/consultants in their own right
- not include any sponsoring or organizing of entertainment events (e.g. sporting or leisure)

Accommodation and venue must:

- maximum be 4 stars
- not be renowned for their entertainment facilities
- not be extravagant or luxurious, e.g. resorts

Flights:

- For professional events to which HCPs or representatives of HCOs have been invited as delegates, economy class must be used. For overseas destinations, economy plus (i.e. "economy flex" or "premium economy") may be used, unless otherwise advised by LEO Pharma.
- For consultants providing professional services, economy class or economy plus should be used. Business class may be used for overseas destinations of more than 6 hours duration, unless otherwise advised by LEO Pharma.

Reimbursement of expenses must only be made for expenses actually incurred and only against original receipts.

4 Tracking the HCP/HCO Transfers of Value

In order for LEO Pharma to be able to live up to its obligations relating to transparency of transfers of value made to HCPs/HCOs by Third Parties, you must:

- insert HCP/HCO information and the related transfers of value details (HCP/HCO spend data) into the **LEO Third Party Transparency Sheet** provided by LEO Pharma, see figure 1
- verify the accurateness and completeness of the HCP/HCO spend data inserted in the LEO Third Party Transparency Sheet
- on the 20th of each month where a payment was made to an HCP/HCO, send the duly completed LEO Third Party Transparency Sheet with the HCP/HCO spend data from the previous month, including documentation as requested by LEO Pharma, to the designated LEO Pharma contact person
- inform LEO Pharma in case of disputes from HCPs/HCOs on the disclosed HCP/HCO spend data

Figure 1. How to complete the LEO Third Party Transparency Sheet

5 Double-blinded activities

A double-blinded activity is an activity where:

- the identity of LEO Pharma is not known to the HCP, and
- the identity of the HCP is not known (and will not be made known) to LEO Pharma.

Sections 2-5 of this LEO Pharma HCP/HCO Compliance Protocol are **not applicable** for such double-blinded activities.

For double-blinded activities, you must ensure the following:

- comply with the ethical codes of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) as well as any other applicable national laws, requirements and/or codes
- only engage with HCPs if there is a legitimate need for the services to be performed by HCPs
- only select HCPs to perform the services based on appropriate qualifications
- ensure that the number of HCPs retained is not greater than the number reasonably necessary to achieve the identified need

- fees and expenses are reasonable and do not exceed fair market value in the country of the HCP; fair market value ranges will be provided by LEO Pharma. If a higher rate is requested, it must be approved in advance by LEO Pharma based on a general description of the qualifications of the HCP without revealing the identity of the HCP
- travel and hospitality must be solely related to the main purpose of the service/activity to be performed
- flights and accommodation cannot be provided in connection with double-blinded activities
- a contract with the HCP is signed prior to initiating the service if required by national laws, requirements and/or codes for this type of service
- reimbursement of expenses must only be made for expenses actually incurred and only against receipts
- HCPs are only engaged for services with the purpose of supporting healthcare or research
- engagements of HCPs must never constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Hospitality must:

- be appropriate and within a reasonable in level
- be strictly limited to travel and meals
- only be provided to persons who qualify as meeting participants/consultants in their own right
- not include any sponsoring or organizing of entertainment events (e.g. sporting or leisure)

Venue must:

- maximum be 4 stars
- not be renowned for their entertainment facilities
- not be extravagant or luxurious, e.g. resorts

For US HCPs:

- no HCPs licensed by the states of Vermont or Minnesota may participate in a market research activity
- determine if the HCPs are employed by federal or state governments that prohibit the HCP's participation in market research
- check that the HCP is not debarred according to the FDA debarment list, and that the HCP is not excluded as per 1) OIG exclusion list and/or 2) GSA exclusion list (SAM).

SIGNATURES **ALLEKIRJOITUKSET** **UNDERSKRIFTER** **SIGNATURER** **UNDERSKRIFTER**

This documents contains 14 pages before this page
Tämä asiakirja sisältää 14 sivua ennen tätä sivua
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authority to sign	toimivaltaoikeus	ställningsfullmakt	autoritet til å signere	myndighed til at underskrive
representative	nimenkirjoitusoikeus	firmateckningsrätt	representant	repræsentant
custodial	huoltaja/edunvalvoja	förvaltare	foresatte/verge	frihedsberøvende